

SFPC-0459

(Translation)

Notice of Reasons for Rejection

Mailing No. : 064236

Mailing Date : February 21, 2006

Patent Application No. Hei 8-507451

Drafting Date: February 15, 2006

To : Mr. Morio Sada  
Applicant's Agent

From: Examiner of Patent Office: Kouichi Seshita 9234 4C00

Suitable article: Article 17, Paragraph 2, (3); Article 29,  
Paragraph 1, Article 29, Paragraph 2;  
Article 36, Article 37

It is deemed that this application should be rejected for the following reason. In case there is any opinion on this action, it is requested that a written comment be submitted within three months from the date on which this notice was mailed.

SFPC-0459

#### Reasons

1. It is deemed that the present application does not satisfy the requirement prescribed in Article 37, with regard to the following points.

2. It is deemed that the Amendment filed on August 8, 2002, does not satisfy the requirements prescribed in Article 17, bis, Paragraph 3, with regard to the following points, i.e., by the reason that the said Amendments are not being prepared within the scope of the matters which are being described in the specification as well as the drawing which were attached firstly to the written application.

3. The present invention disclosed in the following Claims, is deemed to be the same as the invention described in the publication as mentioned in the following documents which was made public in Japan, prior to the filing date of the present application, and therefore, it is deemed that the present invention cannot be granted a patent in accordance with the provisions of Article 29, Paragraph 1, Item 3 of the Patent Law.

4. The present invention disclosed in the following Claim is deemed as one which could have been readily invented by those having ordinary knowledge in the technical field to which said invention belongs, basing on the invention described in the publication as mentioned in the following Remarks which was made public in Japan, prior to the filing date of the present application, and therefore, it is deemed that the present invention cannot be granted a patent in accordance with the provision of Article 29, Paragraph 2 of the Patent Law.

5. It is deemed that the present application does not satisfy the requirements prescribed in Article 36, Paragraphs 6, ii of the Patent Law, owing to the insufficient description of the Claims with regard to the following points.

Note (For cited references, refer to the cited reference list)

5 Reason 1:

A: Claims 1 to 16

\* Remarks:

The invention according to claims 1 to 12 relates to a compound comprising a polymer, a linker, and peptide hormone, and having  
10 a pharmacological activity showing long term efficacy, while the invention according to claims 13 to 16 relates to a novel peptide having a specific amino acid sequence, and therefore the two inventions are not identical in the problems to be solved or in a main portion of the configuration, and have not the relations  
15 as defined in Japanese Patent Law, Article 37, Notes.

This patent application violates the provisions in Japanese Patent Law, Article 37, and therefore examinations for novelty, progressiveness and the like have not be examined for inventions  
20 other than those according to claims 1 to 12.

Reason 2

B. Specification as a whole

\* Remarks

25 In the Amendment, [Glp], [Asp(' -DEA)]<sup>6</sup>, and

[Glp-His-Trp-Ser-Tyr-Gly-Leu-Gln-Pro-Gly-NH<sub>2</sub>], which is GnRH of lampern, used in the specification or drawings attached to the original application (referred to as "original specification") were amended to [pGlu], [Asp(a-DEA)]<sup>6</sup> and  
5 [pGlu-His-Trp-Ser-His-Asp-Trp-Lvs-Pro-Gly-NH<sub>2</sub>] respectively. However, the terms of [pGlu], [Asp(a-DEA)]<sup>6</sup> and [pGlu-His-Trp-Ser-His-Asp-Trp-Lvs-Pro-Gly-NH<sub>2</sub>] are not described in the original specification, and are not anticipated from the terms of [Glp], [Asp(' -DEA)]<sup>6</sup>, and  
10 [Glp-His-Trp-Ser-Tyr-Gly-Leu-Gln-Pro-Gly-NH<sub>2</sub>].

Reason 3:

C: Claims 1-3, 5-12

\* Cited reference 1

15 \* Remarks

Cited reference 1 describes a compound comprising a polymer, a linker, and peptide hormone, and having a pharmacological activity showing long term efficacy, and therefore it is recognized that the invention according to the claims is described in cited reference  
20 1.

Reason 4

D. Claims 1 to 12

\* Cited reference 1-3

25 \* Remarks

The invention according to the claims is different from that described in cited reference 1 in the points that the peptide hormone is a GnRH derivative, and that the linker is a specific oligopeptide. However, the GnRH derivative is described in cited reference 2, and cited reference 3 described a linker which is the specific oligopeptide and links the polymer described in cited reference 1 to a compound having pharmacological activity. Therefore, in expectation of compound having the GnRH derivative described in cited reference 2 and showing long term efficacy, those skilled in the art can easily anticipate employment of the GnRH derivative described in cited reference 2 as a peptide in place of that described in cited reference 1 in the compound comprising a polymer, a linker, and a peptide and having pharmacological efficacy showing long term efficacy described in cited reference 1 and also employment of the specific oligopeptide described in cited reference 3 as a linker. From the descriptions in the specification, it can not be recognized that all of the GnRH derivative hormones, linkers, and polymers provide any specific and remarkable effect surpassing anticipation by those skilled in the art.

Reason 5

E. Claims 1, 9

\* Remarks

The term of "preferably" used in the claims above doubly defines a specific item in the invention, so that the specific

item in the invention according to the claims is not clear.

F. Claims 1, 4, 9, and 12

\* Remarks:

5       The terms of "Ahx", "GnRH-III", "ONp", "OPcp", "Opfp", "ONsu",  
"D-Cpa", and "a-DEA" are used in the claims without any clear  
definition, and the terms make the specific items in the claims  
ambiguous.

(It is to be noted that addition of definitions of the terms  
10 falls in the category of "addition of new matters".)

G. Claims 1 to 12

\* Remarks:

15       The invention according to the claims relates to the compound  
denoted by the formula (I). In the formula (I), however, the  
relation between Y and other portions is not clear, and the portions  
are defined with the terms of "a polymerization-initiating group",  
"an oligopeptide group", and "a peptide hormone group". Namely  
the compound is not specifically defined, and the description is  
20 not appropriate for describing a compound.

For the reasons described above, the invention according  
to claim 1 to 12 is not clear.

25       No reason for rejection has not been found for the invention

according to claims other than those specifically pointed out in this Notice of Rejection. If any new reason for rejection is found, the reason is notified.

5 Cited Reference List

- 1: Japanese patent publication No. HEI 3-505210(WO90/02558)
- 2: J. Cancer Res. Oncol., 1994, Vol. 120, pp.578-584
- 3: International Patent Publication No. 93/14142, pamphlet

10 Record of Prior Art Survey

\* Searched field: IPC 7<sup>th</sup> version

A61K38/22, 47/46, A61P35/00, C07K14/575, 17/00

Database name

CAPLUS(STN), MEDLINE(STN), EMBASE(STN), BIOSIS(STN)

15

\* Prior art document

This record of prior art survey does not constitute any reason for rejection.

20

(Remarks)

The specification includes the expressions of formula "IIa", homolog (IIa), and formula (IIb), but the formulas themselves are not described. Check and amend defective descriptions in the specifications.

25